

# **EXHIBIT 139**

UNITED STATES COURT OF APPEALS  
FOR THE DISTRICT OF COLUMBIA CIRCUIT

WALGREEN COMPANY,  
  
Petitioner,  
  
v.  
  
DRUG ENFORCEMENT  
ADMINISTRATION,  
  
Respondent.

No. 12-1397

Thursday, March 21, 2013

Washington, D.C.

The above-entitled matter came on for oral  
argument pursuant to notice.

BEFORE:

CIRCUIT JUDGES ROGERS AND TATEL, AND SENIOR  
CIRCUIT JUDGE SENTELLE

APPEARANCES:

ON BEHALF OF THE PETITIONER:

GREGORY G. GARRE, ESQ.

ON BEHALF OF THE RESPONDENT:

SAMANTHA L. CHAIFETZ, ESQ.

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THE CLERK: Case number 12-1397, Walgreen Company, Petitioner v. Drug Enforcement Administration. Mr. Garre for the Petitioner; Ms. Chaifetz for the Respondent.

JUDGE ROGERS: Good morning. I would just mention generally that in these cases there are sealed documents, so we would urge Counsel to avoid reference to them unless some other agreement has been reached with the parties, and if the Court's questions veer in that area to just stop us. Thank you.

ORAL ARGUMENT OF GREGORY G. GARRE, ESQ.

ON BEHALF OF THE PETITIONER

MR. GARRE: Thank you, Judge Rogers, and may it please the Court. The immediate suspension order in this case should be set aside because it is based on a significant change in Agency policy that is invalid, both because it represents an unreasonable interpretation of the Agency's own rules, and because it was unaccompanied by notice and comment rule-making, or even the reasoned explanation that the Supreme Court has held is required for an Agency policy change. For --

JUDGE SENTELLE: Do you have to win on the merits of this case to win on the ISO? All we have before us today is the ISO, right?

MR. GARRE: That's absolutely right, Your Honor.

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1 JUDGE SENTELLE: And you seem to be plunging right  
2 into -- aren't you biting off more than you have to chew?

3 MR. GARRE: Well, Your Honor, if there's an easier  
4 route for us to prevail we certainly wouldn't want to  
5 discourage the Court from taking it. What I would say is the  
6 ISO is grounded on a finding of the violation of legal duties,  
7 one of which we think is absolutely invalid, but the duty to  
8 halt, to investigate and halt shipment pending investigation,  
9 and we think that that is a sufficient basis for this Court to  
10 set aside the ISO, the immediate suspension order which has  
11 been in effect for some seven months, and in effect puts a  
12 padlock around a major distribution center for all Schedule II  
13 drugs. Now, this was an extraordinary administrative action  
14 taken without prior notice or an opportunity --

15 JUDGE SENTELLE: Yes. And what's the normal basis  
16 for taking it without prior notice? It's not the validity of  
17 the regulation, it's the immense of harm to the public, isn't  
18 it?

19 MR. GARRE: That's absolutely right, Your Honor.

20 JUDGE SENTELLE: Right.

21 MR. GARRE: Now, we think that --

22 JUDGE SENTELLE: So, when you said a while ago if  
23 there's an easier way to win wouldn't that be the normal way  
24 one would approach an ISO argument?

25 MR. GARRE: Well, and Your Honor, certainly one of

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1 our positions is, is that there is no imminent danger set  
2 forth in the ISO. I think in order to understand the Agency's  
3 thinking of what was an imminent danger, it did base that on a  
4 finding of the statutory violations, and I think that that was  
5 necessary under 824(d), the provision of the statute that  
6 gives the Administrator this extraordinary power. Now, the  
7 Court could disagree with that and still --

8 JUDGE SENTELLE: Well, that might be something they  
9 could find after notice and hearing, but isn't your best  
10 argument on the ISO just it's a due process problem, that  
11 you're entitled to a notice and hearing unless the imminent  
12 element is made?

13 MR. GARRE: That's absolutely right. And our  
14 central --

15 JUDGE SENTELLE: You seem to be coming in here  
16 asking us to invalidate the whole proceeding against you.

17 MR. GARRE: Well, no, Your Honor, because the  
18 revocation proceeding would, presumably could go forward,  
19 although there's no reason why this Court couldn't recognize,  
20 and we think it should recognize that this legal duty that has  
21 been asserted that is a principle basis for the ISO is  
22 invalid. Now, Your Honor is quite right that you could find  
23 other grounds for why the imminency finding is not sufficient.

24 JUDGE SENTELLE: Why should the Court go all the way  
25 to that issue if you could prevail on the other?

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1 MR. GARRE: Well, if we could prevail on the other  
2 ground, Your Honor, the Court would not need to. What I would  
3 respectfully submit is this is an invalid legal duty, it's  
4 clear that it's invalid on the record before you, and for that  
5 reason alone the Court should say that this duty doesn't  
6 exist. There's no reason to have Walgreens or the DEA go  
7 through this extensive proceeding on the basis of a violation  
8 that is improper, and this Court, I think, is well positioned  
9 to say that. You know, having said that we wouldn't  
10 discourage this Court from invaliding the ISO on any ground,  
11 that's the basis we're here today, the ISO.

12 JUDGE TATEL: Well, isn't -- I understood your brief  
13 as saying that the question of notice and comment was an  
14 antecedent question we had to get to because it was, the due  
15 diligence requirement was one of the two elements DEA relied  
16 on for the imminent danger finding, right?

17 MR. GARRE: That's right, Your Honor, we do think  
18 it's --

19 JUDGE TATEL: So --

20 MR. GARRE: We do think it's one of --

21 JUDGE TATEL: Right.

22 MR. GARRE: -- the two. Now, I think --

23 JUDGE TATEL: So, we could say, I suppose we could  
24 say well, even assuming the due diligence requirement is valid  
25 it together with the other finding that is affiliated report,

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1 isn't sufficient for imminent danger finding, we could do  
2 that, right?

3 MR. GARRE: The Court could do that, Your Honor.

4 JUDGE TATEL: But --

5 MR. GARRE: But I think that the --

6 JUDGE TATEL: But -- yes. I see. Right.

7 MR. GARRE: But I think that the Court is still  
8 presented before it with an ISO which is grounded in principle  
9 part on the violation of a legal duty that unquestionably  
10 represents a significant change in the law. There are many  
11 cases in which the Court may have to speculate on that, but  
12 here it has the sworn testimony of a senior DEA official that  
13 this was, quote, a significant change in DEA policy, DEA --

14 JUDGE TATEL: Who was that official, by the way?

15 MR. GARRE: Your Honor, it was Kyle Wright, he was  
16 an office in the Office of Diversion Control. He was the  
17 Agent that the DEA put forward in this other case to testify  
18 about its regulatory policies.

19 JUDGE ROGERS: He was like the number two supervisor  
20 because he reported to somebody named Marx (phonetic sp.), I  
21 think.

22 MR. GARRE: He was within, there are several leading  
23 officials within the Office of Diversion Control, he  
24 ultimately reported to the Deputy Director of --

25 JUDGE ROGERS: All right.



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1 MR. GARRE: -- the DEA, and he was the person that  
2 the DEA put forth in that case to testify about it. And the  
3 District Court in that case made findings that this was a  
4 significant change, and about his testimony that were not  
5 challenged on appeal, in fact, the Government abandoned appeal  
6 in that case. So, certainly we think that -- and with respect  
7 to this issue of the change, again, to be clear we have two  
8 arguments on this, one is we don't think that this  
9 interpretation is reasonable at all under the Agency's  
10 regulations because the Agency's regulations specifically  
11 establish a reporting requirement, but not this additional  
12 investigate and halt shipment requirement, and we think that  
13 follows from the analysis that this Court set forth in the  
14 *Ethyl Corp.* case. But the second argument is, is even if they  
15 could convince the Court that this was somehow a plausible  
16 interpretation, an agency can't undertake this sort of  
17 significant policy change without going through notice and  
18 comment rule-makings required by cases like *Paralyzed*  
19 *Veterans*, the *Alaska Professional Hunters* case, so that in  
20 itself is independent defect. And it gets even worse for the  
21 Agency because under the Supreme Court's recent decision in  
22 *FCC v. Fox Television* we know that at the bare minimum the  
23 Agency has to both recognize the change and provide reasoned  
24 explanation for that change. The Agency has never attempted  
25 that here, its position before this Court is --

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1 JUDGE TATEL: But that would only, that would only,  
2 that principle would only come into play if notice and comment  
3 weren't required, right?

4 MR. GARRE: Yes.

5 JUDGE TATEL: Okay. So, again, let's go back to the  
6 antecedent --

7 JUDGE ROGERS: Right.

8 JUDGE TATEL: -- issue here, or to use that word  
9 again. So, the way to think about this, I take it, is first,  
10 see if you think I have this right, the first question is was  
11 it a change that required notice and comment, right? Second,  
12 even if it didn't was it an unexplained change, right? Are  
13 those separate?

14 MR. GARRE: I think they are separate --

15 JUDGE TATEL: Yes.

16 MR. GARRE: -- ground, either would be sufficient to  
17 say that --

18 JUDGE TATEL: Right.

19 MR. GARRE: -- the manner they went about this --

20 JUDGE TATEL: Yes.

21 MR. GARRE: -- was invalid under the APA. But we  
22 think that there's a threshold issue, Your Honor, which is  
23 that there's no room for this interpretation at all under  
24 their own regulations given the way that the regulations are  
25 set up, which is to say in 1301.71(a) that the Administrator

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1 shall use these specific requirements to determine whether or  
2 not there had been --

3 JUDGE TATEL: But isn't that the notice and comment  
4 point? In other words, they could add this due diligence,  
5 they would just have to do it through notice and comment rule-  
6 making, right?

7 MR. GARRE: No, Your Honor --

8 JUDGE TATEL: No?

9 MR. GARRE: -- it's not. It's the argument that the  
10 regulations preclude this all together. And you can sort of  
11 stop there without getting --

12 JUDGE TATEL: Well, can't they change their  
13 regulation?

14 MR. GARRE: They can, Your Honor, they can going  
15 through notice and comment.

16 JUDGE TATEL: Right.

17 MR. GARRE: And it goes to their point that they can  
18 do this without notice and comment. And our point on that is  
19 they can't because it's precluded by the regulations, the text  
20 of their own regulations, it's an unreasonable interpretation.

21 JUDGE TATEL: But they can change their regulations.

22 MR. GARRE: But they can change it through notice  
23 and comment.

24 JUDGE TATEL: Through notice and comment, so they  
25 could --

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1 JUDGE ROGERS: So, we're back to notice and comment.

2 JUDGE TATEL: Right. They could if they had

3 authority under the statute to add this due diligence

4 requirement. They could do it through notice and comment.

5 MR. GARRE: Ultimately they could, Your Honor.

6 Obviously, they have not undertaken that, and what they have

7 here is an administrative order grounded on the violation of a

8 duty that is quite simply --

9 JUDGE TATEL: And from your perspective --

10 MR. GARRE: -- unlawful.

11 JUDGE TATEL: Yes, from your perspective the reason

12 for us to address that question first, notice and comment, as

13 opposed to the merits of the imminent danger finding I think

14 is that you have the merits hearing ahead of you, right?

15 MR. GARRE: No, that's --

16 JUDGE TATEL: And --

17 MR. GARRE: Your Honor, we think it's a sufficient

18 ground to say that this order was contrary to law. Now, once

19 you got into the merits, if by that you refer to the findings,

20 and we think that there are several flaws with the order on

21 its own. It's based on a broad assumption that all orders

22 which may have originated from pain clinics were illegitimate;

23 it's based -- if you look at the order very carefully, all of

24 the allegations of wrongdoing take place in 2010 and 2011, yet

25 this order is issued in September of 2012. And then if you

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1 look at paragraphs 20 and 21 of the order you find that the  
2 only basis that they actually identify in 2012 for believing  
3 that there's a harm is that Walgreens is the biggest  
4 distributor in the state, and that the average sales from  
5 Walgreens stores are slightly, are higher than the average  
6 sales, national sales for pharmacies, which of course include  
7 many mom and pop pharmacies, so those figures are absolutely  
8 meaningless in establishing an imminent danger in September,  
9 2012.

10           The other thing that they pointed to was the failure  
11 to comply with the reporting requirement. Now, we do  
12 recognize that that is a requirement in the regulations,  
13 that's not a sufficient basis to uphold this order because the  
14 order was based on so many other invalid reasons under  
15 *Chenery*, this Court has to send it back and have the Agency  
16 consider it. But even with respect to the reporting  
17 violations I want this Court to understand that the reason why  
18 Walgreens stopped making those reports in 2012 is because its  
19 changed its reporting system so that orders were automatically  
20 cut off at the pharmacy level before they even got to the  
21 distribution level. During the same period, moreover,  
22 Walgreens was making the so-called ARCOS reports to the DEA on  
23 a monthly basis, that's acknowledged, of all its inventory and  
24 all its orders during this period. And during this period  
25 it's undisputed I think, and the ISO recognized Walgreens had

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1 made substantial reductions in the amount of orders going to  
2 these pharmacies, some 75 percent. And if you look at the  
3 chart on page 23 of our brief it shows a dramatic drop off in  
4 the distribution, so we think it's simply unfounded even if  
5 this Court goes to the merits that there was an imminent  
6 danger in September of 2012 when this order was issued, and  
7 for any of those basis this extraordinary administrative act  
8 should be set aside. If I could reserve the remainder of my  
9 time.

10 JUDGE ROGERS: Thank you.

11 MR. GARRE: Thank you. Good morning.

12 ORAL ARGUMENT OF SAMANTHA L. CHAIFETZ, ESQ.

13 ON BEHALF OF THE RESPONDENT

14 MS. CHAIFETZ: Good morning, Your Honors, may it  
15 please the Court, Samantha Chaifetz for the Department of  
16 Justice and the Drug Enforcement Administration.

17 Plaintiff's case challenges, concedes to begin with  
18 the reporting failures that the DEA Administrator --

19 JUDGE TATEL: Would you mind starting with the  
20 notice and comment --

21 MS. CHAIFETZ: Sure.

22 JUDGE TATEL: -- questions? And focus on that. And  
23 specifically, Walgreen's argument that this new requirement,  
24 that the due diligence requirement is new and required notice  
25 and comment rule-making, that it's not covered by existing

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1 regulation. Not included in it.

2 MS. CHAIFETZ: Right. So, to take the first  
3 point --

4 JUDGE TATEL: Yes.

5 MS. CHAIFETZ: -- the suggestion that this is a new  
6 requirement.

7 JUDGE TATEL: Yes.

8 MS. CHAIFETZ: The conduct at issue in the case,  
9 we're talking about distributing practices beginning really in  
10 2009 through 2012. Now, back in 2006 there's no dispute that  
11 letters were issued by DEA, guidance letters, that went out to  
12 all the distributors, Walgreens included, explaining that they  
13 were, DEA was in these letters reiterating responsibilities  
14 incumbent upon distributors, and sorry, the first of these  
15 letters was September, 2006, okay, telling distributors saying  
16 we think you're already well aware, that's a quote from the  
17 letter, of these responsibilities, but we are reiterating  
18 them.

19 JUDGE TATEL: But the question is whether those  
20 notices, whether --

21 JUDGE ROGERS: Guidance.

22 JUDGE TATEL: -- notice and comment rule-making was  
23 required to authorize those notices.

24 MS. CHAIFETZ: Well, notice and comment rule-making  
25 would only be required --

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1 JUDGE TATEL: Yes.

2 MS. CHAIFETZ: -- if we were marking an amendment, a  
3 change from a pre-existing regulation.

4 JUDGE TATEL: Well, the argument is --

5 MS. CHAIFETZ: The regulation --

6 JUDGE TATEL: The argument is that that's exactly  
7 what happened here, that this regulation says the Agency shall  
8 consider, and it lists a bunch of things, and it doesn't list  
9 anything else, and unlike other regulations it doesn't say it  
10 shall consider these and such other factors.

11 MS. CHAIFETZ: Right. Your Honor --

12 JUDGE TATEL: Right? So --

13 MS. CHAIFETZ: -- it certainly says that the DEA  
14 shall consider a variety --

15 JUDGE TATEL: Right.

16 MS. CHAIFETZ: -- of factors, and those factors are  
17 things like the size of the vault in which substances are  
18 held, et cetera. Those factors must be considered, there's no  
19 dispute about that.

20 JUDGE ROGERS: But let me just --

21 MS. CHAIFETZ: What the regulation --

22 JUDGE ROGERS: Let me just --

23 MS. CHAIFETZ: -- does not say -- sorry, Your Honor.

24 JUDGE TATEL: No, but --

25 JUDGE ROGERS: Please, go ahead.



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1 MS. CHAIFETZ: What the regulation does not say is  
2 that that is in any sense an exclusive list, it simply says  
3 that those things shall be considered.

4 JUDGE ROGERS: So, if --

5 MS. CHAIFETZ: DEA never interpreted -- yes, Your  
6 Honor?

7 JUDGE ROGERS: Go ahead.

8 MS. CHAIFETZ: DEA never interpreted that regulation  
9 to be exclusive. There is no point in history, not even in  
10 the Kyle Wright testimony cited by opposing counsel, where DEA  
11 has ever suggested that that list was exclusive. Now, in --

12 JUDGE TATEL: But you see, in the same regulation,  
13 in exactly the same regulation, subsection 34 it says in  
14 determining whether an importer, et cetera, et cetera, against  
15 diversion the Administrator shall consider among other  
16 factors, and then it lists them. So, in the same regulation  
17 you have the Agency saying for one standard you shall consider  
18 in this case specific things, and in this other one specific  
19 items among other factors.

20 MS. CHAIFETZ: That's right. There are --

21 JUDGE TATEL: Isn't that a pretty clear indication  
22 that at least for, with respect to --

23 MS. CHAIFETZ: No, Your Honor --

24 JUDGE TATEL: No?

25 MS. CHAIFETZ: -- because here what we're dealing

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1 with is not a statute that lists a bunch of broad --

2 JUDGE TATEL: You mean a regulation.

3 MS. CHAIFETZ: A regulation, rather, a regulation  
4 that lists a broad set of factors to be considered. We're  
5 talking about a regulation that identifies some very specific  
6 physical security controls that need to be looked at. To step  
7 back for a moment, what we're talking about here on DEA's part  
8 is not an expectation of some obscure responsibility on the  
9 part of the distributors, we are talking about distributors  
10 who have in front of them a suspicious order, an order they  
11 themselves have recognized as suspicious, and the question is  
12 what does the distributor need to then do? Should they simply  
13 distribute --

14 JUDGE TATEL: You're missing --

15 JUDGE SENTELLE: No, what the regulations require --

16 JUDGE TATEL: Yes, you're --

17 JUDGE SENTELLE: -- them to do?

18 JUDGE ROGERS: To do.

19 JUDGE TATEL: You're not responding --

20 MS. CHAIFETZ: Well, we have a statute here --

21 JUDGE TATEL: You're not responding --

22 MS. CHAIFETZ: We have a -- sorry?

23 JUDGE TATEL: You're not responding to my question.

24 I would agree with you about the word shall, if that's all we  
25 had. If it said you shall do this, that doesn't mean you

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1 can't do other things. But the question I'm asking you is  
2 that in the same regulation another provision says shall  
3 consider among other factors, and the question I was asking  
4 you was doesn't the inclusion of among other factors in the  
5 same regulation for another provision suggest that among other  
6 factors was not included in this one? That's my only  
7 question.

8 MS. CHAIFETZ: Well, my point, Your Honor, is  
9 that --

10 JUDGE TATEL: Yes.

11 MS. CHAIFETZ: -- those other regulations are in  
12 many cases looking at then broad factors.

13 JUDGE TATEL: I see.

14 MS. CHAIFETZ: And what we're talking about here,  
15 what the DEA is instructed to look at are not broad factors,  
16 but very specific requirements that would not be in any sense  
17 apparent from the face of the statute, such as the number of  
18 inches thick a container for controlled substances must be to  
19 pass muster. Whereas, what we're talking about here in this  
20 case is the very self-evident expectation that if you have in  
21 front of you an order that sends up red flags for diversion  
22 controls, and you have a statutory responsibility as a  
23 registered distributor to maintain effective controls against  
24 diversion, and as DEA explained in the 2007 *Southwood*  
25 decision, you have a responsibility to ensure that you're not

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1 willy-nilly sending out orders without regard to the red flags  
2 you yourself have observed, well then, you know, this --

3 JUDGE TATEL: Well, that's --

4 MS. CHAIFETZ: -- is something that's flowing  
5 directly from the statute, and --

6 JUDGE TATEL: From the statute, but the question  
7 here is whether the regulation has been written in a way that  
8 confines the Agency to the specified standards. In other  
9 words, you may well be right that the regulation can be  
10 lawfully amended to include this, but the argument that the  
11 Petitioner is making is that the way the regulation is written  
12 is that it confines the Agency to the specified factors.

13 MS. CHAIFETZ: And that has never been DEA's  
14 interpretation of its own regulation, and they cite no  
15 evidence to the contrary. The only times that DEA has spoken  
16 it has loud and clear explained that it did expect -- now,  
17 prior to 2006 we simply have no comment from DEA, there's no  
18 established Agency regulation, no formal statement, but in  
19 2006 we have the first guidance letter putting in writing what  
20 DEA had thought was evident, reiterating these  
21 responsibilities, and talking about this expectation. Then in  
22 2007, though, we have the *Southwood* decision, and we have the  
23 *Novelty* decision, both formal adjudications which both  
24 expressly recognize this responsibility. The *Novelty*  
25 decision, DEA says a distributor has an affirmative duty to

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1 forego a transaction if upon investigation it's unable to  
2 determine that the transaction is for legitimate purposes.  
3 The *Southwood* decision we, of course, discuss at length in our  
4 brief. Later that year you have another letter going out  
5 reiterating these responsibilities, emphasizing in that one  
6 the need for timely reporting of suspicious orders, something  
7 else that Walgreens here, the Jupiter Center, failed to do.

8 Now, you know, the only evidence that they point to  
9 to suggest that this is a change of policy is this testimony  
10 during a civil asset forfeiture proceeding, a bankruptcy case  
11 where the question presented to the Court was not one about  
12 interpreting the CSA, but about looking at whether a  
13 distributor should have known certain things. And Kyle  
14 Wright's testimony speaks to what had before 2006 in his  
15 opinion been the enforcement policies and practices of DEA --

16 JUDGE SENTELLE: Before we let you sit down --

17 MS. CHAIFETZ: -- but it was not an official --

18 JUDGE SENTELLE: Before we let you sit down, I think  
19 you've been over this part, I would like to know what your  
20 best argument is for the truncating of the proceeding. That  
21 is to say the ISO. The imminent danger.

22 MS. CHAIFETZ: Yes. Yes.

23 JUDGE SENTELLE: You can't just go out and act  
24 without due process.

25 MS. CHAIFETZ: That's right. This Court has

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1 concluded that when proceedings are done in accord with the  
2 statutory provision at 824(d)(4) immediate suspension orders,  
3 there is not a due process problem.

4 JUDGE SENTELLE: You understand my question is what  
5 your basis is for imminent danger in this case? Not what this  
6 Court has held as a general proposition.

7 MS. CHAIFETZ: Absolutely. Your Honor, in this case  
8 we have the Jupiter Center, the largest distributor of  
9 Oxycodone in Florida.

10 JUDGE SENTELLE: I know they're big. I know they've  
11 done --

12 MS. CHAIFETZ: Okay.

13 JUDGE SENTELLE: -- bad things in the past, but now  
14 there are two stages to litigation, or I know you allege  
15 they've done bad things. Normally --

16 MS. CHAIFETZ: Absolutely.

17 JUDGE SENTELLE: -- you would have to prove that  
18 after notice and hearing.

19 MS. CHAIFETZ: Well, we have --

20 JUDGE SENTELLE: If you can show an imminent danger  
21 then you can proceed with an ISO. Now, as I read the charts  
22 and the numbers in the record, the massive distribution had  
23 dropped off dramatically. The best response I got from the  
24 Government was well, they only did that after they were  
25 charged. I don't know why that would matter in determining

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1 imminent danger, that might go to the ultimate resolution, but  
2 so far as determining imminent danger I don't see what the  
3 imminent danger is that you're relying on for the use of the  
4 ISO without the *Mathews v. Eldridge* process.

5 MS. CHAIFETZ: As the ISO acknowledges there was a  
6 drop off in numbers among, you know, for example, the top  
7 eight stores where Walgreens cut off completely --

8 JUDGE SENTELLE: That goes to a reason not --

9 MS. CHAIFETZ: No.

10 JUDGE SENTELLE: -- to use the ISO, there was a drop  
11 off.

12 MS. CHAIFETZ: Well --

13 JUDGE SENTELLE: Now, give me the reason why you do  
14 use the ISO, how you do justify it.

15 MS. CHAIFETZ: So, what I'm saying, Your Honor, is  
16 that the reason for the ISO, to step back the numbers here  
17 were a huge red flag for DEA, and frankly, for Walgreens, as  
18 well. The record --

19 JUDGE SENTELLE: You're jumping the subject, again.  
20 They were a huge red flag, all right, this goes to merit, that  
21 goes to merit, but normally you would have to establish those  
22 merits with *Mathews v. Eldridge* process.

23 MS. CHAIFETZ: So, I just wanted to lay out the  
24 chronology, but --

25 JUDGE SENTELLE: We know that.

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1 MS. CHAIFETZ: -- to move forward --

2 JUDGE SENTELLE: Yes.

3 MS. CHAIFETZ: -- Your Honor, after this notation of  
4 this huge red flag of the numbers began the DEA investigation.  
5 Okay. So, now DEA issues the warrants, goes in, interviews  
6 staff, subpoenas documents, the findings --

7 JUDGE SENTELLE: Do any of those things --

8 MS. CHAIFETZ: -- of that investigation --

9 JUDGE SENTELLE: -- justify an ISO?

10 MS. CHAIFETZ: Absolutely, Your Honor. Absolutely.

11 JUDGE SENTELLE: The fact that you issue --

12 MS. CHAIFETZ: It's that --

13 JUDGE SENTELLE: Excuse me.

14 MS. CHAIFETZ: -- yes.

15 JUDGE SENTELLE: Counsel, whoa. The fact that the  
16 Agency issues a subpoena can't possibly justify an ISO.

17 MS. CHAIFETZ: Oh, no, Your Honor.

18 JUDGE SENTELLE: The fact that the --

19 MS. CHAIFETZ: I apologize, that's not --

20 JUDGE SENTELLE: -- conducts an investigation --  
21 will you please quit interrupting us? The fact that the  
22 Agency conducts an investigation can't possibly justify an  
23 ISO. What I want to know is what is the imminent danger that  
24 gets you past the requirement for due process?

25 MS. CHAIFETZ: You have a facility here that DEA



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1 found had none of the essential protective systems to control  
2 against diversion. The statute places a great emphasis for  
3 good reason the need to prevent diversion. You didn't have  
4 here staff that were trained in how to identify orders, you  
5 had a schedule two manager at the Jupiter facility who said it  
6 wasn't her job to do any kind of due diligence when it came to  
7 suspicious orders. You have a center that abdicates its  
8 responsibility to report suspicious orders, which DEA has  
9 repeatedly noted is crucial to preventing harm to the public.  
10 So, Your Honor, I do apologize for my meandering narrative,  
11 but what I was trying to highlight for you is that the numbers  
12 are only a small part of the story, they're the trigger here,  
13 they raise significant concerns because they are so high, and  
14 they remain high, and though they come down for certain stores  
15 where Jupiter imposes this blunt approach of simply cutting  
16 off schedule two operations, that's not the same as remedying  
17 the systematic shortcomings that were so worrisome to DEA, and  
18 those systematic shortcomings are in part undisputed here,  
19 there's no dispute about the shortcomings with regard to  
20 reporting or detecting suspicious orders, and then there's no  
21 dispute --

22 JUDGE TATEL: This is a distribution center, right,  
23 not a pharmacy, correct?

24 MS. CHAIFETZ: It's a distributor.

25 JUDGE TATEL: Yes.

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1 MS. CHAIFETZ: It's a distributor, yes.

2 JUDGE TATEL: So, I hear what you're saying in  
3 response to Judge Sentelle's question, namely that the problem  
4 here is the failure to perform due diligence, and to do the  
5 reporting, right? What's the difference between that and the  
6 ultimate decision about suspension? In other words, is what  
7 the Agency is saying is that any failure to report, and any  
8 due diligence defects are in addition to being a ground for  
9 revocation, a ground for an imminent danger finding, is that  
10 your point? Because --

11 MS. CHAIFETZ: No, Your Honor.

12 JUDGE TATEL: Well, what is the difference?

13 JUDGE SENTELLE: Yes.

14 MS. CHAIFETZ: Our point here --

15 JUDGE TATEL: I don't see in this any difference. I  
16 see a potentially solid basis for an ultimate revocation, but  
17 what I don't see in the record, and the only thing you have,  
18 the Agency has are the due diligence and reporting failures  
19 for a distribution center. What in that adds to the imminent  
20 danger finding? That's what I don't understand.

21 MS. CHAIFETZ: If you had these failures, these same  
22 failures occurring --

23 JUDGE TATEL: Right.

24 MS. CHAIFETZ: -- at a tiny distributor with a very  
25 small distribution, a mom and pop distributor of sorts,

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1 perhaps that wouldn't rise to the level of imminent danger.

2 JUDGE SENTELLE: So, you're saying that any time  
3 there's --

4 MS. CHAIFETZ: But here --

5 JUDGE SENTELLE: -- a violation by a large  
6 distributor you get an ISO?

7 MS. CHAIFETZ: No, I'm saying that where you have a  
8 distributor who's distributing the kinds of quantities of  
9 dangerous schedule two through five controlled substances, but  
10 specifically Oxycodone, that Jupiter was distributing you  
11 really do have a very serious concern for public safety. I  
12 mean --

13 JUDGE TATEL: But they closed --

14 MS. CHAIFETZ: -- to put this in perspective --

15 JUDGE TATEL: -- they suspended the eight stores  
16 with the most serious problems, and they say, and you don't  
17 disagree in your, they say in the blue brief that DEA has no  
18 evidence about diversion at any other store, and in your brief  
19 you didn't challenge that.

20 MS. CHAIFETZ: I'm not sure, when you talk about  
21 evidence of diversion, DEA did not have the resources --

22 JUDGE TATEL: I mean, isn't that what an imminent  
23 danger is?

24 MS. CHAIFETZ: Well, DEA did not do the kind of in  
25 depth investigation at all 800 and, nearly 850 Florida

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1 pharmacies that the Jupiter Center distributes to. Where DEA  
2 focused its investigation it found tremendous indicators of  
3 diversion. I mean, we're talking about a company that --

4 JUDGE TATEL: And the company suspended those  
5 stores.

6 MS. CHAIFETZ: Well, it suspended them in May, 2012  
7 after the administrative inspection warrants were served.

8 JUDGE TATEL: Then why should that make a  
9 difference? I mean --

10 MS. CHAIFETZ: Well --

11 JUDGE TATEL: -- the question is is there or is  
12 there not an imminent danger?

13 JUDGE SENTELLE: Yes.

14 MS. CHAIFETZ: One of the, the concern here about  
15 imminent danger is do we have --

16 JUDGE TATEL: What could reduce the imminent danger  
17 more than suspending the stores?

18 MS. CHAIFETZ: Do we have a distributor, the  
19 question here for DEA was are we dealing with a distributor  
20 who can be trusted as a registrant to protect the public  
21 interests, or do we think that their continued registration is  
22 causing imminent danger? And the conclusion was this was a  
23 threat to the public safety, an imminent threat because this  
24 was a distributor that was not taking any of its  
25 responsibilities to protect the public safety serious, and the

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1 time line confirms that.

2 JUDGE SENTELLE: Normally those things would be  
3 determined in a due process hearing, and you seem to be  
4 establishing a line that says any time we charge a major  
5 violation we get an ISO, and I don't see any other line you're  
6 going for.

7 MS. CHAIFETZ: No, Your Honor, there have been,  
8 there are many instances in which we don't charge ISOs in  
9 conjunction with orders to show cause, and some of the  
10 Walgreens pharmacies are examples of that. But here just to  
11 put these things in perspective, right, this is a company that  
12 asserted in letters to DEA back in January, back in May, 2012  
13 saying look, we're vertically integrated, we may not have, you  
14 know, whether or not, they've essentially asserted whether or  
15 not things happened at the distributor there was due diligence  
16 adequately occurring at the pharmacies, or perhaps at  
17 headquarters. But then when we turned to look at the things  
18 that were happening at the pharmacies we find that due  
19 diligence wasn't happening. Instead what we find are some of  
20 the examples cited in the ISO, you have pharmacies with, you  
21 know, arrests going on in the parking lot, you have people  
22 being, seeing drugs passed inside the pharmacy, people being  
23 arrested on the premises. The police chief of Oviedo sending  
24 letters to everyone at Walgreens up the chain to the CEO and  
25 chairman begging for help, and what is the Jupiter Center

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1 doing, continuing to distribute large amounts, ever increasing  
2 amounts.

3 The point of these narratives is that we do have  
4 large numbers going out to lots of stores outside of the top  
5 six, even in 2012 when they claim that their numbers have come  
6 down so much. If you look, for example --

7 JUDGE SENTELLE: Well, you don't contend --

8 MS. CHAIFETZ: -- at the top 25 --

9 JUDGE SENTELLE: -- that they're wrong about that.

10 MS. CHAIFETZ: Sorry?

11 JUDGE SENTELLE: You concede that their numbers have  
12 come down, you said.

13 MS. CHAIFETZ: Well, we concede that they cut off  
14 the --

15 JUDGE SENTELLE: You concede their numbers have come  
16 down considerably, right or wrong?

17 MS. CHAIFETZ: It's really -- we do acknowledge --

18 JUDGE SENTELLE: Okay.

19 MS. CHAIFETZ: -- that they were able to bring down  
20 the numbers by taking certain measures. But it's important to  
21 recognize the huge increase that we saw, at one point 20  
22 percent of that increase, 19 percent, was a result of the top  
23 six stores. So, what do they do, they cut off those stores  
24 completely, that doesn't tell us anything about whether or not  
25 they have the kind of controls needed to prevent diversion

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1 going to all the other stores where we still see distributions  
2 happening in 2012 to those stores that are more than a  
3 standard deviation away from the mean. You've got --

4 JUDGE ROGERS: So, can I just be --

5 MS. CHAIFETZ: -- a national average --

6 JUDGE ROGERS: May I just be clear, the controls  
7 you're talking about is the due diligence and stop shipments?

8 MS. CHAIFETZ: The due diligence and the stop  
9 shipments certainly speak to the important controls, but  
10 suspicious order reporting is another terrifically important  
11 part of this that they don't dispute they weren't doing  
12 because that's what facilitate DEA field officials being able  
13 to carry out the kinds of investigations necessary to stop  
14 diversion. This is a closed regulatory scheme in which DEA  
15 allows people to participate, registers them to make these  
16 distributions with the understanding that everyone as  
17 explained in the letters, in the *Southwood* decision, and in  
18 *Novelty* that everyone's going to contribute to monitoring the  
19 system. And here what we had was a distribution center that  
20 because this is an integrated company tried to say well, look  
21 to the pharmacies to do it, or look to headquarters to do it,  
22 and then when DEA looks to those places and finds that the  
23 controls aren't in place they turn around and say well, that's  
24 a problem at the pharmacy, that's not a problem with us. I  
25 mean --

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1 JUDGE ROGERS: All right.

2 MS. CHAIFETZ: -- they're to hide the ball --

3 JUDGE ROGERS: All right.

4 MS. CHAIFETZ: -- here I think in a critical way.

5 JUDGE ROGERS: Anything further? New argument?

6 MS. CHAIFETZ: New arguments?

7 JUDGE ROGERS: No, I mean in terms of we're sort of  
8 repeating ourselves here.

9 MS. CHAIFETZ: Well --

10 JUDGE TATEL: Can I, I have one question.

11 JUDGE ROGERS: And you're way over time.

12 JUDGE SENTELLE: Way over.

13 JUDGE TATEL: I have one question, is that okay?

14 JUDGE ROGERS: All right.

15 JUDGE TATEL: It's a procedural, it's a new  
16 question.

17 JUDGE ROGERS: Good.

18 JUDGE TATEL: New subject. I'm already getting into  
19 the next case, right? So, if we agree with Petitioner that  
20 the adoption of the due diligence requirement was the fact  
21 that either because it needed notice and comment, or because  
22 it was an unacknowledged change, just assume that we think  
23 that, do you agree then that this has to be vacated because  
24 there's no indication in the Agency's decision that the other  
25 basis for the imminent danger finding, namely the affiliated



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1 report, was an independent one, do you agree with that?

2 That's what they say in their reply brief.

3 MS. CHAIFETZ: Your Honor, they do assert that. No,  
4 Your Honor, the --

5 JUDGE TATEL: They don't?

6 MS. CHAIFETZ: -- suspicious order, the failures  
7 there they try in their brief to suggest that this is a mere  
8 technicality --

9 JUDGE TATEL: No, no, no, that wasn't my question.

10 MS. CHAIFETZ: -- and should be set aside.

11 JUDGE TATEL: No.

12 MS. CHAIFETZ: No, I understand.

13 JUDGE TATEL: That isn't my question.

14 MS. CHAIFETZ: But I think those are connected.

15 JUDGE TATEL: But --

16 JUDGE ROGERS: No, do you understand his question?

17 JUDGE TATEL: -- just focus on my specific question.

18 In *Novelty* where we did sustain it because it was other, the  
19 Agency had said that the other factor was, quote, reason alone  
20 for the order. Whereas, here as I read the order it looks to  
21 me like the two factors are a combined analysis. I didn't see  
22 any indication, and you can correct me about this if you want,  
23 that the Agency was telling us that there are independent  
24 basis for an imminent danger finding.

25 MS. CHAIFETZ: The Agency certainly, the ISO

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1 certainly explains why the suspicious order requirement is a  
2 tremendously important one.

3 JUDGE TATEL: Right.

4 MS. CHAIFETZ: And so, though there is not a line in  
5 the ISO that --

6 JUDGE TATEL: Right.

7 MS. CHAIFETZ: -- expressly states that that alone  
8 would be significant enough to justify an imminent danger  
9 there's not that text. What there is is an explanation of the  
10 fact that the worry here is that we have a distributor --

11 JUDGE TATEL: I agree with all that. But you, I  
12 hear you conceding --

13 MS. CHAIFETZ: And that worry --

14 JUDGE TATEL: -- I hear you conceding --

15 JUDGE ROGERS: Conceding.

16 JUDGE TATEL: -- that they are not, there's nothing  
17 in this that says these are two --

18 JUDGE ROGERS: We would have done it anyway.

19 JUDGE TATEL: -- independent basis, right?

20 MS. CHAIFETZ: There is not that line, but I think  
21 it's --

22 JUDGE TATEL: I haven't missed something?

23 MS. CHAIFETZ: -- a fair reading of the decision to  
24 understand, and worth understanding that the suspicious order  
25 requirement --

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1 JUDGE TATEL: Okay. That's all I have.

2 MS. CHAIFETZ: -- speaks to the broader concern, and  
3 therefore --

4 JUDGE TATEL: That's my only question.

5 JUDGE ROGERS: All right.

6 JUDGE TATEL: Thank you.

7 JUDGE ROGERS: Thank you.

8 MS. CHAIFETZ: Thanks very much.

9 JUDGE ROGERS: Thank you. All right. Counsel for  
10 Appellant here, or --

11 ORAL ARGUMENT OF GREGORY G. GARRE, ESQ.

12 ON BEHALF OF THE PETITIONER

13 MR. GARRE: Thank you, Your Honors. Just a few  
14 brief points. On the last point, Judge Tatel, not only does  
15 the order not provide anything like for this reason alone, as  
16 was true in *Novelty*, it says at the very end on page J.A. 28  
17 in view of the foregoing.

18 JUDGE ROGERS: Right.

19 MR. GARRE: And that underscores that this order was  
20 based on everything, the violation of the completely new and  
21 invalid investigate and halt shipment duty is all throughout  
22 those paragraphs, six, 10, 11, 12, 22 and 24 all rely on that  
23 explicitly. So, this order would have to be set aside if this  
24 Court agrees with us that that was an invalid change of  
25 interpretation.

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1 JUDGE ROGERS: So, from your point of view, just so  
2 I'm clear, the change, or the new requirements that you say  
3 required notice and comment, that alone would be grounds for  
4 setting aside the ISO since your client was not required to do  
5 those things under law?

6 MR. GARRE: Absolutely, Your Honor, under *Chenery*  
7 and other decisions of this Court the Court would have to send  
8 the order back because --

9 JUDGE ROGERS: And so, we need not venture into an  
10 examination of what must be shown for imminent danger? I just  
11 want to be clear about that.

12 MR. GARRE: That's right, Your Honor, the Court  
13 would be saying that you cannot base an ISO on a violation of,  
14 alleged violation of invalid legal duty.

15 With respect to what I think Your Honors have  
16 referred to the merits today, I would just close by saying  
17 that the critical paragraphs in the ISO are paragraphs 20 and  
18 21, and in those paragraphs the Administrator first recognizes  
19 that Walgreens had made substantial reductions in the  
20 distributions to the key stores that the DEA itself had  
21 focused on. It's never provided evidence of any diversion  
22 with respect to other stores. That reduction is shown  
23 markedly on the chart that appears on page 196 of the Joint  
24 Appendix and this brief. And then it goes on to the next  
25 paragraph 21 to try to explain the harm that's existing today,

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1 and all it points to is the fact that the Walgreens is the  
2 biggest distributor in the state, and has distribution above  
3 the national average. It's not a violation of the Controlled  
4 Substances Act to be big, and it's not enough to base this  
5 kind of extraordinary action on a finding of past harm,  
6 Congress required a finding of imminent danger, and this order  
7 is completely lacking in establishing that necessary  
8 predicate.

9 JUDGE ROGERS: Thank you.

10 MR. GARRE: If there are no further questions we  
11 would urge this Court to act quickly. Thank you.

12 JUDGE ROGERS: Thank you.

13 (Recess.)  
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DIGITALLY SIGNED CERTIFICATE

I certify that the foregoing is a correct transcription of the electronic sound recording of the proceedings in the above-entitled matter.



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Paula Underwood

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March 26, 2013

DEPOSITION SERVICES, INC.